K051680

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SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTED BY: DYNATRONICS CORPORATION
7030 Park Centre Drive
Salt Lake City UT 84121
Phone: (800) 874-6251; (801) 568-7000; Fax: (801) 568-7711

1. DEVICE NAME (Trade/common, and classification): Dynatron® DX2™ Combination Traction Unit and Infrared Therapy.

   Classification: Class II
   Regulation Nos.: 890.5900; 890.5500
   Product Codes: ITH, ILY

2. PREDICATE DEVICES:

   Dynatron 900 Traction Unit – cleared under K993919
   Lordex Power Traction Unit - cleared under K031227
   Dynatron 705 - cleared under K031329

3. PERFORMANCE STANDARDS: The Dynatron DX2 device conforms to the applicable requirements of 21 CFR sections 1010 (Performance Standards for Electronic Products: General).

4. DESCRIPTION:

   Components:

   System console, model Dynatron DX2, containing electric motor and control electronics with LCD alpha-numeric display.

   Pull-head or Goniometer attaches patient harnesses and applied force. Feedback from the Goniometer displays force applied and angle of force.

   Accessories such as traction belts.

   Output ports on the back of the DX2 system console accommodate infrared therapy devices such as the Dynatron D880 (K031329) and Dynatron D890 (K040729).

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5. INTENDED USE/INDICATIONS FOR USE: The Dynatron DX2 is designed to provide static, intermittent, and cycling distraction forces to relieve pressures on structures that may be causing low back pain. It relieves pain associated with herniated discs, protruding discs, degenerative disc disease, posterior facet syndrome, and sciatica. It achieves these effects through decompression of intervertebral discs, that is, unloading due to distraction and positioning.

   The Dynatron DX2 functions as a system console for controlling the use of infrared therapy devices such as the Dynatron D880 and Dynatron D890 devices. Indications for Use of these devices are to provide topical heating for temporary increase in blood circulation, temporary relief of minor muscle and joint aches, pains and stiffness, relaxation of muscles, muscle spasms, and minor pain and stiffness associated with arthritis.

   The Intended Use/Indications For Use stated herein are consistent with the cleared indications for the predicate devices.

6. SUBSTANTIAL EQUIVALENCE (SE) RATIONALE: The Dynatron DX2 shares the same or similar basic characteristics, features and intended use as the predicate devices and, therefore, is substantially equivalent to the Dynatron 900 Traction Unit and the Lordex Power Traction Unit (applicable 'K' numbers listed above) and the Dynatron 705 system console function for controlling infrared therapy devices.

7. SAFETY AND EFFECTIVENESS: There are no substantive differences between the products defined in this 510(k) submission and the predicate device. They are similar to the technologies that are currently used in other similar medical devices. They were developed and documented under Dynatronics' mature Quality Management System, under the Quality System Regulation, 21 CFR Part 820, under design/change control, and are verified/validated to applicable standards/guidance documents. The products, and accessories, are safe and effective, when used as indicated in specific applications under a clinician's supervision/therapy program.

Signed: _____ Dated: _____

Ronald J. Hatch, VP Operations/RA
DYNATRONICS CORPORATION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 1 2005

Ron Hatch
Vice President Operations/Regulatory Affairs
Dynatronics Corporation
7030 Park Center Drive
Salt Lake City, Utah 84121

Re: K051680
Trade/Device Name: Dynatron® DX2
Regulation Number: 21 CFR 890.5900
Regulation Name: Power traction equipment
Regulatory Class: II
Product Code: ITH, ILY
Dated: September 23, 2005
Received: September 26, 2005

Dear Mr. Hatch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051680

Indications for Use

510(k) Number (if known): K051680

Device Name: Dynatron® DX2

Indications for Use:

The Dynatron DX2 is designed to provide static, intermittent, and cycling distraction forces to relieve pressures on structures that may be causing low back pain. It relieves pain associated with herniated discs, protruding discs, degenerative disc disease, posterior facet syndrome, and sciatica. It achieves these effects through decompression of intervertebral discs, that is, unloading due to distraction and positioning.

The Dynatron DX2 also functions as a system console for controlling the function of infrared therapy devices such as the Dynatron D880 (K031329) and the Dynatron D890 (D040729). Indications for use of these infrared therapy devices are to provide topical heating for temporary increase in blood circulation, temporary relief of minor muscle and joint aches, pains and stiffness, relaxation of muscles, muscle spasms, and minor pain and stiffness associated with arthritis.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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